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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,221	PHALIPON ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence letter*.

Lack of Unity/Election/Restrictions

Claims 1-43 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a plurality of conjugate molecules that vary in saccharide structure and conjugate structure.
Group II, claim(s) 18-23, drawn to a plurality of saccharide molecules which differ in size and chemical structure.
Group III, claim(s) 24-29, 34-35, drawn to a plurality of antibodies of different specificities and structure, and may include SEQ ID NO. 12-34.
Group IV, claim(s) 30-32, 33 drawn to a plurality of polynucleotides that encode parts or whole antibodies, expression vector and host cell; a transgenic animal or a transgenic plant that comprises the polynucleotide.
Group V, claim(s) 36-43, drawn to a plurality of processes of preparing conjugates.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Based upon the international search report that sets forth six "X" references and nine "Y" references that anticipate or obviate the first appearing invention, the instant claims are not so linked to define a shared common special technical feature that makes a contribution over the prior art, and therefore lack Unity of Inventions. The claimed embodiments evidence differences in chemical structure, function and biological effect thus defining patentably independent or distinct inventions.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I species, saccharide formula component A, carrier component B- Please select a single saccharide formula and a single component B carrier: ie: PADRE, Protein T-cell epitope, Peptide T-cell epitope, Tetanus toxoid , or biotin.

Group II species: please select a single saccharide formula for search.

Group III: Please select an antibody for search: ie: one of the Deposited antibodies, a chimeric antibody that contains portions of the Deposited antibodies represented by SEQ ID NOs 12-34, or fragments of monoclonal antibodies represented by SEQ ID NOs 12-34.

Group IV species (select the desired combination of component A & B) : select component A: the desired polynucleotide that encodes the desired combination of SEQ ID NOs from 12-34 , select component B: a host cell comprising the polynucleotide, or a host cell modified by a vector, or a transgenic animal or a transgenic plant.

Group V: select the desired formula for use in the claimed process of preparation.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: No claims are generic

4. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art,

the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

1. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The instant Specification sets forth a hyperlink on page 129, line 20, paragraph [0446]; it should be removed.

3.

Sequence Compliance/Sequence Requirements

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

- Claim 4 recite the petide "PADRE"; this should have a sequence identifier inserted next the amino acid sequence.
- Table G at page 134 describes SYA/J6 by six amino acid SEQ ID NOs 12, 35 to 39 and F22-4 by six SEQ ID NOs 12, 16, 20, 24, 28 and 32, but Table G shows **7 peptide** sequences (see below, "PM" and "DY", being two separate peptides) for F22-4; Clarification/Correction of Table G is required.

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Table G: Comparison of the sequences of SYA/J6 (SEQ ID NO: 12, 35 to 39) and F22-4 (SEQ ID NO: 12, 16, 20, 24, 28 and 32) CDRs*

VH	H1	H2	H3
	31 35	52abc	100a
SYA/J6	NYWMS	EIRLKSNNYATHYAESVKG	GGAVGAMDY
F22-4	NYWMS	EIRLKS**D**NYAT**Y**YAESVKG	PM DY

VH	L1	L2	L3
	27abcde 30	50 56	89 97
SYA/J6	RSSQSLLHSDGNTYLH	KVSNRFS	SQTTHVPT
F22-4	RSS**K**SLLHSDGITYL**Y**	**H**LSN**L**AS	AHNVELPRT

* Kabat numbering

5. Please see Notice to Comply.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: See listing below:

- Figure 1 shows the numbers 104, 109, 113 and 114 which are not described in the figure nor in the Brief Description of the Drawings on page 44 of the Specification.
- Figure 2 shows the numbers 102, 113, 118 and 119 which are not described in the figure nor in the Brief Description of the Drawings on page 44 of the Specification.
- Figure 3 shows the numbers 102 and 118 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 4 shows the numbers 102, 105, 125 which are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.

- Figure 8 shows the number 204 and letters a, b and c, which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 9 shows the letters a, b and c which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 10 shows the letters a, b and c and the numbers 208, 212, and 214 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 11 shows the letters a, b and c and the number 301, 309- 313 are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 12 shows the letters a-f and the numbers 309- 310 are not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 13 shows the number 314 which is not described in the figure or in the Brief Description of the Drawings on page 45 of the Specification; the Brief Description of the Drawings describes the synthesis of pentasaccharide 313 which is not mentioned or shown in Figure 13.
- Figure 14 shows the numbers 323, and 311 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 15 shows the numbers 311, 321 and 316 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 16 shows the letters a, b and c and the number 346 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.

- Figure 18 shows the number 405 and the letter “h” which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 19 shows the designator “SAMA-Pfp” the meaning of the term is not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 20 shows the letters a-h which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 21 shows the letters a-g which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 22 shows the letters a-i which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 23 shows the letters a-c which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- Figure 25 shows the letters a-h and numbers 608-609 which are not described in the figure nor in the Brief Description of the Drawings on page 45 of the Specification.
- Figure 26 shows the letters a-f and numbers 606-608 which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- Figure 27 shows the letter a and numbers 606-607 and 617which are not described in the figure nor in the Brief Description of the Drawings for this drawing on page 45 of the Specification.
- Figure 28 shows the terms "{}=BIOT" and “BIOT” which are not described in the Brief Description of the Drawings for this drawing on page 45 of the Specification; the Brief Description of the Drawings describes the synthesis of conjugates 701-713, but figure 28

only describes conjugates 701-706 and 708-713, number 707 is not a saccharide but the BIOT carrier.

- ❖ Figure 28bis is described in the Brief Description of the Drawings as showing the synthesis of conjugate number 801, but the arrows are directed in the chemical degradation of conjugate 801, to the component parts, and is therefore not the synthesis but degradation of conjugate 801; the description is not directed to what is shown in figure 28bis.
- ❖ Figure 34 shows six frames, 34A, B, C, D, E, F and G, but are not labeled as such, nor described based upon each frame shown in the figure based upon what was administered. The Brief Description of the Drawings is incomplete, and the Figure should be labeled for clarity of data presented.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

General Observations

8. The instant claim set has a plurality of improper dependent claims. Generally, a multiple dependent claim is a dependent claim which refers back in the alternative to more than one

preceding independent or dependent claim. The second paragraph of 35 U.S.C. 112 has been revised in view of the multiple dependent claim practice introduced by the Patent Cooperation Treaty. Thus 35 U.S.C. 112 authorizes multiple dependent claims in applications filed on and after January 24, 1978, as long as they are in the alternative form (e.g., "A machine according to claims 3 or 4, further comprising ---"). Cumulative claiming (e.g., "A machine according to claims 3 and 4, further comprising ---") is not permitted. A multiple dependent claim may refer in the alternative to only one set of claims. A claim such as "A device as in claims 1, 2, 3, or 4, made by a process of claims 5, 6, 7, or 8" is improper. 35 U.S.C. 112 allows reference to only a particular claim. Furthermore, a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. These limitations help to avoid undue confusion in determining how many prior claims are actually referred to in a multiple dependent claim. A multiple dependent claim which depends from another multiple dependent claim should be objected to by using form paragraph 7.45.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
August 24, 2010

/Mark Navarro/
Primary Examiner, Art Unit 1645